

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH
CAROLINA CHARLOTTE DIVISION
Civil Action No.: 3:18-CV-00320-KDB-DSC**

LARADA SCIENCES, INC.,

Plaintiff,

vs.

PEDIATRIC HAIR SOLUTIONS
CORPORATION and FLOSONIX
VENTURES, LLC,

Defendants.

CLAIM CONSTRUCTION ORDER

In this action, Plaintiff Larada Sciences (“Larada”) asserts patent infringement claims against its former licensee Defendant Pediatric Hair Solutions Corp. and Defendant FloSonix Ventures, LLC (collectively “PHS”) related to several patents involving methods / devices for eliminating ectoparasite (lice) infestation. Very broadly stated, the patented inventions involve “applying sufficient airflow directly to the scalp at a temperature/airflow/time combination that does not burn the skin” so that “substantially all of the ectoparasites can be killed effectively.” The parties disagree on the construction of several claim terms of U.S. Patent Nos. 7,789,902 (“the ‘902 Patent”); 8,162,999 (“the ‘999 Patent”); and 8,475,510 (“the ‘510 Patent”) and also disagree on the definition of who should be considered a “person having ordinary skill in the art.” The parties have fully briefed their respective proposed constructions and the Court held a “Markman” claim construction hearing, including a tutorial on the patents at issue, on August 15, 2019.

Having carefully considered the parties’ arguments, the patents at issue and other relevant intrinsic evidence of record, the Court construes the disputed terms of the ‘902 Patent, ‘999 Patent and ‘510 Patent and determines who should be considered a person of ordinary

skill in the art of those patents as follows:

I. A “PERSON OF ORDINARY SKILL IN THE ART”

“A court construing a patent claim seeks to accord a claim the meaning it would have to a person of ordinary skill in the art at the time of the invention.” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). The Federal Circuit has held that a person of skill in the art is “a hypothetical person who is presumed to know the relevant prior art.” *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citing *Custom Accessories Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986)). In determining the level of ordinary skill, district courts may consider the “type of problems encountered in the art, prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1376 (Fed. Cir. 2012) (quoting *Custom Accessories*, 807 F.2d at 962).

The parties’ descriptions of who should be considered a person having ordinary skill in the art (“PHOSITA”) are similar, with one key difference. Larada contends that:

For the ’902, ’999, and ’510 Patents, a person of ordinary skill in the art at the time of the invention would have at least a bachelor’s degree in mechanical or biomechanical engineering, or equivalent coursework, at least a year of experience developing medical devices and/or personal care devices involving the delivery of heat and/or airflows to human and/or non-human animal patients, and at least a year of experience in developing and/or providing treatments to alleviate the effects of ectoparasite infestations in human and/or non-human animal patients.

PHS contends:

For the ’902, ’999, and ’510 Patents, a PHOSITA at the time of the invention would have at least a bachelor’s degree in mechanical or biomechanical engineering, **entomology**, or equivalent coursework, at least a year of experience developing medical devices and/or personal care devices involving the delivery of heat and/or airflows to human and/or non-human animal patients, and at least a year of experience in developing and/or providing treatments to alleviate the effects of ectoparasite infestations in human and/or non-human animal patients. Less work experience may be compensated by a higher level of education, such as a Master’s degree, and vice versa. (emphasis added).

Thus, the parties' disagreement is whether or not a PHOSITA must have "at least a bachelor's degree in . . . entomology." Larada's argument is that a degree in entomology (the study of insects) would not be necessary to "determine whether the temperature/airflow/time combination is within the claimed ranges, or to recognize when ectoparasites are dead." Whether someone without an entomology degree can understand or apply the patent is, however, not the test of who is a PHOSITA (plainly, the Court and the jury will need to do so to some degree, but that does not mean that they all have "ordinary" or any skill in the art).

In its argument, PHS correctly points out that a number of the problems encountered in the art are those in entomology. The problems that the alleged inventions of the '902, '999, and '510 Patents attempt to solve are related to eliminating ectoparasites such as head lice (*i.e.*, insects) and the prior art solutions to these problems are in the field of entomology. *See, e.g.*, '902 Patent ("References Cited"); '510 Patent (same). PHS also points out that while the entomology degrees of Dr. Clayton (an inventor for the '902 and '999 Patents), is "by no means conclusive" those degrees are relevant because "the educational level of the inventor may be a factor in determining the level of ordinary skill in the art." *Orthopedic Equip. Co. v. All Orthopedic Appliances*, 707 F.2d 1376, 1382 (Fed. Cir. 1983).

Nevertheless, given the requirement in both parties' descriptions that the PHOSITA must have at least a year of specific work experience in the field of the invention, *i.e.*, specifically related to the eradication of ectoparasites, a bachelor's degree in entomology may not be necessary for someone to be a PHOSITA. Rather, the combination of longer relevant work experience with the other qualifications may be a sufficient substitute for an academic degree in entomology, which in any event would be broader than is necessary to be a person of "ordinary" skill in the relevant art.

Therefore, the Court finds that a "person of ordinary skill in the art" for the purposes of this action is defined as follows:

For the '902, '999, and '510 Patents, a person having ordinary skill in the art at the time of the invention would have at least a bachelor's degree in mechanical or biomechanical engineering, entomology, or equivalent coursework, at least a year of experience developing medical devices and/or personal care devices involving the delivery of heat and/or airflows to human and/or non-human animal patients, and at least a year of experience in developing and/or providing treatments to alleviate the effects of ectoparasite infestations in human and/or non-human animal patients. Alternatively, a person having ordinary skill in the art may have 18 months of the stated work experience in the absence of a bachelor's degree in entomology. Also, less work experience may be compensated by a higher level of education, such as a Master's degree.

II. LEGAL STANDARDS GOVERNING CLAIM CONSTRUCTION

Analysis of patent infringement involves two steps. “The first step is determining the meaning and scope of the patent claims asserted to be infringed.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995) (en banc). “The second step is comparing the properly construed claims to the device accused of infringing.” *Id.* It is the first step, “commonly known as claim construction or interpretation,” that is at issue at the present stage of this case. *Id.*

It is the court's role in claim construction to “analyze the text of the patent and its associated public record and apply the established rules of construction, and in that way arrive at the true and consistent scope of the patent owner's rights to be given legal effect.” *Markman*, 52 F.3d at 979. “It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotations omitted). Thus, the goal of claim construction is to determine the meaning of the claims. *See id*; *O2 Micro Int'l Ltd. V. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008).

“To ascertain the meaning of claims,” the court must consider primarily the “intrinsic record,” comprised of “the claims, the specification, and the prosecution history.” *Markman*, 52 F.3d at 979; *Phillips*, 415 F.3d at 1313. Prosecution history is the “public record” of proceedings in the Patent and Trademark Office, which may include statements by the inventor, or on his behalf, while

a patent application is pending approval. Secondly, the court may consider “extrinsic evidence” in the form of expert testimony, technical information and dictionaries. *Id.*

To start, “the claim construction analysis must begin and remain centered on the claim language itself.” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). This Court must “look to the words themselves ... to define the scope of the patented invention.” *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

The “words of a claim are generally given their ordinary and customary meaning.” *Phillips*, 415 F.3d at 1312 (quotations omitted). However, a claim term’s “ordinary and customary” meaning is not necessarily the same as its “common” public meaning. Rather, the “ordinary and customary” meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1313. A person of ordinary skill in the art “is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field.” *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998). Where the ordinary meaning of a claim phrase or term is not apparent, a court may then act as would a person of ordinary skill in the art by looking to “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Innova/Pure Water*, 381 F.3d at 1116.

When engaging in claim construction, courts must follow a hierarchy of evidence, with the first being claim language, the second consisting of other intrinsic evidence (i.e., the specification, the remainder of the patent, and the prosecution history), and the third being extrinsic evidence (i.e., evidence that is external to the patent and prosecution history, such as expert testimony or treatises). *Advanced Cardiovascular Sys. v. Medtronic*, 265 F.3d 1294, 1304 (Fed. Cir. 2001). This

hierarchy of evidence does not, however, suggest that courts must consider and weigh all forms of evidence. Instead, if the intrinsic evidence provides a court with sufficient evidence to inform the claim construction, it need not descend and consider extrinsic evidence.

When a court considers intrinsic evidence, the specification is “the single best guide to the meaning of a disputed term” and most often “dispositive.” *Phillips*, 415 F.3d at 1315. Courts must be cautious, however, to avoid limiting the scope of the claims by importing limitations of the specification into the scope of the claims. There is “a fine line between reading a claim in light of the specification and reading a limitation into the claim from the specification.” *Id.* at 1323. Where a court construes “the claims based on the written description, the district court has committed one of the cardinal sins of patent law—reading a limitation from the written description into the claims.” *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001). Rather, “[c]laims must be read in view of the specification, of which they are a part.” *Id.* (citation and quotations omitted). Notably, the patentee need not “describe in the specification every conceivable and possible future embodiment of his invention.” *CCS Fitness v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)(internal citations omitted).

Also, “the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.* at 1317. Nevertheless, the court cannot “rely on the prosecution history to construe the meaning of the claim to be narrower than it would otherwise be unless a patentee limited or surrendered claim scope through a clear and unmistakable disavowal.” *3M Innovative Properties v. Tredegar Corp.*, 725 F.3d 1315, 1322 (Fed.Cir.2013).

III. DISPUTED CLAIM CONSTRUCTIONS

Claim terms that at least one party contends require construction are set out below.

The parties agree that all other terms do not require construction and the jury should be informed that these terms have their plain and ordinary meaning.

(1) U.S. Patent Nos. 7,789,902 (the ‘902 Patent) and 8,162,999 (the ‘999 Patent)

TERM 1:

	TERM (Patent: claims)	LARADA’S PROPOSED CONSTRUCTION	PHS’S PROPOSED CONSTRUCTION
1	<p>“heating a volume of air to a temperature to form heated air at a temperature of from about 54° C. [sic] to about 65° C.” (’902: 1-12, ’999: 1-10)</p> <p>“heating a volume of air to a temperature of from about 54° C. [sic] to about 65° C. to form heated air” (’902:14-28, ’999:11-20)</p> <p>“the temperature of the volume of air is from about 54° C to about 59° C” (’902: 5, 15, 23; ’999: 3, 12, 18)</p>	Plain and Ordinary Meaning	<p>Indefinite.</p> <p>If not indefinite, then the plain and ordinary meaning of this claim term is:</p> <p>“heating a volume of air to a temperature of from 54° C to 65° C [59° C]¹ to form heated air at a temperature from 54° C to 65° C [59° C].”</p>

The patents’ claims related to the temperature of the heated air used to eradicate the lice are a core part of the claims of the ‘902 and ‘999 Patents. The fundamental disagreement among the parties related to the construction of those claims is whether the patents’ use of the term “about” in

describing the components of the required temperature range (e.g., “about 54° C”) makes the patents “indefinite.”

Larada’s position – which is the same as its position with all of the disputed claim terms – is that the words used in the challenged “temperature terms” are “common” words easily understandable to a PHOSITA and therefore there is no need for the Court to construe the claim terms beyond holding that the words have their “plain and ordinary” meaning. More specifically, Larada contends that, “the term ‘about’ . . . is a descriptive term commonly used in patent claims to ‘avoid a strict numerical boundary to the specified parameter.’” *See, e.g., Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001) (quoting *Pall Corp. v. Micron Seps.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995)).

A patent must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention.” 35 U.S.C. § 112 ¶ 2 (2006). *See* 35 U.S.C. § 112. “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, ____ U.S. ____, 134 S.Ct. 2120, 2124 (2014). Defendants carry the burden of showing invalidity due to indefiniteness. *See Apple Inc. v. Samsung Electronics Co.*, 786 F.3d 983, 1003 (Fed. Cir. 2015). A patent is presumed valid under 35 U.S.C. § 282 and, “consistent with that principle, a [fact finder is] instructed to evaluate ... whether an invalidity defense has been proved by clear and convincing evidence.” *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91 (2011).

Prior to the Supreme Court’s decision in the *Nautilus* case, a claim was indefinite when it was “insolubly ambiguous” or “not amenable to construction.” *Datamize*, 417 F.3d at 1347 (internal

quotations and citations omitted). In *Nautilus II*, the Supreme Court observed that § 112, ¶ 2 requires “a delicate balance.” 134 S.Ct. at 2128 (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002)). On one hand, the court noted, the definiteness requirement must consider the inherent limitations of language. “Some modicum of uncertainty,” the court recognized, is the “price of ensuring the appropriate incentives for innovation.” *Id.* (quoting *Festo Corp.*, 535 U.S. at 741). On the other hand, the court explained, a patent must be precise enough to afford clear notice of what is claimed, thereby “appris[ing] the public of what is still open to them. Otherwise there would be a zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims.” *Id.* at 2129 (internal quotation marks and citations omitted). The court further explained another policy rationale: “absent a meaningful definiteness check ... patent applicants face powerful incentives to inject ambiguity into their claims.” *Id.*

Balancing these competing interests, the Supreme Court held that “[t]o determine the proper office of the definiteness command, ... we read § 112, ¶ 2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with *reasonable certainty*.” *Id.* (emphasis added). “The standard adopted” by the Supreme Court “mandates clarity, while recognizing that absolute precision is unattainable.” *Id.* at 2129. It also accords with opinions of the Court stating that “the certainty which the law requires in patents *is not greater than is reasonable*, having regard to their subject-matter.” *Id.* (quoting *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 270 (1916) (emphasis added)).

“In the face of an allegation of indefiniteness, general principles of claim construction apply.” *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed.Cir.2010) (internal quotation marks and citation omitted). “In that regard, claim construction involves consideration of

primarily the intrinsic evidence, *viz.*, the claim language, the specification, and the prosecution history.” *Id.*

PHS contends that the temperature range limitations of the ’902 and ’999 Patents’ claims are neither particular nor distinct because the claims include an inherent term of degree – “about” – that makes it impossible for a PHOSITA to determine the scope of the claimed temperature range with a reasonable certainty. PHS argues that neither the claims nor the more detailed specifications provide an approximation, standard, or method for measuring the degree of “about” for a temperature value so a PHOSITA would not know with a reasonable certainty whether any specific temperature outside the stated range (such as 53.8° C, 52.9° C or 51° C) would be “about 54° C,” as recited in the claims.

Terms of degree often pose definiteness concerns because they are inherently vague and, while these terms have common meaning, they arguably take on a technical meaning within the context of the patent. However, “[t]here is no blanket prohibition on terms of degree. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1374 (Fed. Cir. 2014); *see Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1378 (Fed.Cir.2015) (“We do not understand the Supreme Court to have implied in [Nautilus], and we do not hold today, that terms of degree are inherently indefinite). “Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention.” *Id.* (quotations omitted). In addition, “[t]he degree of precision necessary for adequate claims is a function of the nature of the subject matter.” *Id.* at 1382. Thus, in determining whether a term of degree makes a claim term indefinite (thus invalidating the patent as to that claim term and all the other claims that depend on it), “the court must determine whether the patent provides some standard for measuring that degree”

to provide enough certainty to a PHOSITA as to the scope of the claim. *See Biosig Instruments*, 783 F.3d at 1378.

PHS argues that “nothing in the specification or file histories of the ’902 and ’999 Patents provide any indication of whether temperatures that are close to, but not within, the specifically claimed temperature ranges satisfy the claim language. In response, Larada argues that it would be improper to rewrite the claims to omit the word “about” because claims should be “interpreted with an eye toward giving effect to all terms in the claim”), *see Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). Also, Larada asserts that the term “about” “commonly appears in patent claims ... and district courts typically construe ‘about’ to have its plain and ordinary meaning, find construction unnecessary, or construe it to mean ‘approximately.’”¹

While there is no specific guidance in the specifications concerning how to measure the acceptable variation from the stated temperature range permitted by the term “about” – that is, there is no mathematical formula which can be applied – the Court will strike the balance suggested by the Supreme Court in favor of holding that the inclusion of the term “about” does not render the Patents indefinite and thus invalid. However, the Court will construe the term “about” to mean “within one degree of,” which is an alternate construction suggested by Larada during oral argument.

The prosecution history of the Patents as well as information in the specifications related to the variance for the range of air velocities disclosed in the Patents counsels in favor of this conclusion. During the prosecution of the Patents, the patent examiner rejected Larada’s initial proposed patent claims – which included a broader range of temperatures from 50° C to 100° C – as unpatentable because of an earlier patent, U.S. 5,261,427, to Dolev (the “Dolev” patent). The patent

¹ The parties have each cited to cases in which “about” has either been found to be definite or indefinite on the particular facts of those cases, although it is fair to say that Larada has cited to more authority in support of its position. However, because the Court’s inquiry must be focused on both the specific facts of the patents at issue and the nature of the invention reflected in the patents, the Court does not find any of the cited authority to be controlling or highly instructive.

examiner, over Larada's objections, found that Dolev already disclosed the invention of using a combination of heated air, air velocity and time to eradicate lice thus making Larada's proposed patents unpatentable "specially in light of the lack of any disclosed criticality for a special relationship between the ranges of time, temperature, and airflow as evidenced by the large values disclosed." July 17, 2009 PTO office action. Later, in a telephone conference between Larada and the patent examiner on December 15, 2009, the patent examiner again reiterated her conclusion that Larada's "extremely large ranges" for time, temperature and airflow were problematic and suggested, "that the focus of the claims be shifted from the application of the heated air to airflow with narrower airflow ranges as it seems from discussion that the invention is aimed at low heat and high airflow." In response to these discussions, Larada amended its proposed patent claims on January 18, 2010 "as suggested by the Examiner during the interview ... to recite a more specific combination of heat and airflow ranges."

There are several conclusions that may be drawn from this history. First, there is no question that Larada intended to significantly narrow its claims by the final amendments that it made to obtain the patent. Indeed, in making the amendments to the temperature ranges, Larada said that the amendments were presented "without prejudice to the reintroduction of the previous claims, or other broader claims, in a subsequent application." Therefore, Larada should not be permitted to use the "about" claim term to recapture the broad ranges which it disclaimed in the patent office. Second, while the patent examiner clearly believed that the ranges for temperature, airflow and time needed to be narrowed, there is no evidence that the examiner believed that patentability should depend on small differences in these ranges. In other words, the prosecution history does not suggest that a range of 54°C to 65°C would be acceptable, but a similar 11 degree range of 53°C to 64°C or even a slightly broader range of 54°C to 66°C would not have been patentable over Dolev. So, the Court does not find, as PHS contends, that Larada "disclaimed" 50°C to 54°C and 66°C to 100°C. Rather,

it is more accurate to conclude that Larada disclaimed “about” a 50°C temperature range for “about” a 11°C range, but did not disclaim any particular temperature values above and below those stated in the patent claims.

Further, the patent examiner did not raise any issue with the inclusion of “about” in any of the proposed ranges, even though that term appeared in the proposed claims throughout the patenting process. Finally, the patent examiner recognized, as would a PHOSITA, that none of the ranges for heat, airflow or time would be independently determinative. Rather, the effective *combination* of the elements of airflow, temperature and time would be infinitely variable, with more airflow allowing for lower heat, for example. Again, this suggests that relatively small changes within any particular range would not be considered critical by a PHOSITA, who could thus determine that “about” would likely encompass only small differences from the stated temperature range.

The specification of the ‘902 Patent similarly suggests the magnitude of the small changes to the suggested ranges that would be within the ambit of the “about” term of degree. In the context of discussing different methods of airflow measurements, the specification discloses a variance of +/- 5%. While this variance is unrelated in the literal sense to temperature, it would give a PHOSITA some standard to understand the small degree of variation that was considered acceptable in another of the elements being combined in the invention. Applying this amount of +/- 5% to the 11°C range of temperature values suggests a variance of +/- .055°C. However, neither the patent specifications nor the prosecution history suggests that “about” should be construed to involve fractions of degrees or temperatures more specific than whole degrees. During oral argument Larada’s counsel stated that because of the patents’ use of whole degrees, “within one degree” of the stated temperature ranges would be “about” / “extremely close to” the values in the claims and that Larada did not object to construing “about” in that manner.

Therefore, a PHOSITA would be able to, with reasonable certainty (but not the mathematical precision requested by the Defendants), determine that a particular temperature is “about” the stated temperature range in the ‘902 and ‘999 Patents if it is “within one degree” of 54°C to 65°C. Thus, PHS has not established that this claim term is “indefinite” by “clear and convincing” evidence, and the Court construes the claim term to mean:

“heating a volume of air to a temperature within one degree of the range of 54° C to 65° C to form heated air within one degree of the temperature range from 54° C to 65° C”

TERM 2:

	TERM (Patent: claims)	LARADA’S PROPOSED CONSTRUCTION	PHS’S PROPOSED CONSTRUCTION
2	<p>“an airflow of from about 25 cfm to about 125 cfm” (’902: 1-12, 14-28; ’999: 13)</p> <p>“airflow is from about 50 cfm to about 125 cfm” (’902: 16, 22)</p> <p>“an airflow of from about 20 cfm to about 125 cfm” (’999: 20)</p>	Plain and Ordinary Meaning	<p>Indefinite</p> <p>If not indefinite, then the plain and ordinary meaning of this claim term is: “an airflow from 25 cfm [20 cfm or 50 cfm] to 125 cfm +/- 5 cfm”</p>

The construction of the second set of disputed terms also involves the issue of “indefiniteness,” but this time in the context of the ranges of “airflow” rather than temperature. PHS challenges the definiteness of the airflow range for two reasons. The first reason is a similar challenge to the “about” term of degree discussed above; however, with respect to this term PHS suggests that the term can be construed to use the +/- 5cfm range mentioned in the specification

(discussed above) to avoid the claim term being indefinite.

The second, different reason offered by PHS for why the airflow ranges are indefinite is its argument that the patents allegedly do not convey with reasonable certainty how to measure airflow. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015) (holding claim indefinite where there were three different ways to measure molecular weight yielding different results and the patent and prosecution history did not show which measure to use); *see also Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620, 630 (Fed. Cir. 2015) (“The patent and prosecution history must disclose a single known approach or establish that, where multiple known approaches exist, a person having ordinary skill in the art would know which approach to select”).

Specifically, PHS alleges that the patents discuss different methods mentioned for measuring airflow (pitot tube, bulk volumetric and Bernoulli Flow Meter) which give different airflow values and the patents do not endorse a particular method; therefore, a PHOSITA would not know whether a particular airflow is within the ranges described in the patents if different methods of measurement might put an airflow both inside and outside the patented range.

In response, Larada argues that the patents do in fact endorse a particular method of airflow measurement – the bulk volumetric method – and thus are not indefinite. According to Larada,

“Defendants ignore the specification’s clear teaching that of the four types of airflow measurement considered, the inventor relied on the ‘Bulk Volumetric Method.’ *See* ’902 Patent at 2:64-3:20; 11:64-12:59; 12:61-13:14; and 13:54-57, Examples 1-5, and Table 1. ... Indeed, the specification makes clear that of the four types of measurements considered, one (“pitot tube” measurement) was inaccurate, one (manufacturer’s self-reported information) was untrustworthy, and a third (“Bernoulli’s Thin Plate Orifice Flow-meter”) could not be used in all situations. This leaves only the bulk volumetric measurements as the method the inventors relied on.

The Court agrees with Larada that the Patents provide sufficient guidance to a PHOSITA to determine that the bulk volumetric method is preferable and would be the appropriate measuring

standard for the airflow ranges in the Patents. *See* ‘902 Patent at 11:51-53 (“It is believed that such volumetric measurements may provide a more accurate description of reported airflow range values”); ‘902 Patent at 13:52-53 (“the Bulk Volumetric method is simple and greatly reduces both experimental and calculational error.”).²

At oral argument, PHS argued that while the ‘902 Patent expresses a preference for “volumetric” measurements, the examples given for volumetric measurements were “non-limiting” and that the “Bernoulli flow meter” is also a “volumetric” measurement so merely expressing a preference for “volumetric” measurements does not make the ‘902 Patent sufficiently definite. First, the ‘902 Patent clearly expresses a preference for the Bulk Volumetric method in the specifications; the fact that other volumetric measurements might be used that approximate that measurement method does not make the patent indefinite. *See CCS Fitness*, 288 F.3d at 1366 (the patentee need not “describe in the specification every conceivable and possible future embodiment of his invention.”). Second, it is not clear from the specifications whether or not the “Bernoulli flow meter” is also a “volumetric” measurement and neither party presented evidence to clarify the issue. However, the specification does state that the Bernoulli flow meter was “used to validate the data derived from the Bulk Volumetric method” and that “the two methods utilize different principles,” *see* ‘902 Patent at 13:54-58. Thus, the reference to the Bernoulli flow meter appears to be only a secondary and different method that approximated the preferred Bulk Volumetric method rather than an equal substitute for it.

The point of the definiteness inquiry is to determine if a PHOSITA would be able to know, with reasonable certainty, whether a particular airflow velocity is within or outside the claims of the

² Given these statements of preference for volumetric measurements in the patents, Larada could not in any event credibly contend that an airflow value that is outside the range for infringement under the bulk volumetric measurement method is within the range under a different method so that the patent is infringed.

patent. The Court finds that reading the preference for the Bulk Volumetric method stated in the specifications, a PHOSITA would be able to know with reasonable certainty that if a given airflow velocity is within the range of the values in the patent measured by the Bulk Volumetric method or by another method that is within +/- 5 cfm or 5% of the Bulk Volumetric method then the airflow is within the claim language in dispute. This is sufficiently definite to avoid PHS's argument that the language is "indefinite."

Accordingly, the Court finds that the airflow range terms are not indefinite and that the Court can construe these patent terms in light of the specifications which, as acknowledged by PHS, provide a standard +/- 5 cfm (~ 5%) for measuring the degree of the term "about" with respect to airflow measurements. Thus, these claim terms are construed to mean:

"an airflow from 25 cfm [20 cfm or 50 cfm] to 125 cfm +/- 5 cfm (~ 5%)"

(2) U.S. Patent No. 8,475,510 ('510 Patent)

TERM 3 (referenced as Term 5 in the parties' briefing)³:

	TERM (Patent: claims)	LARADA'S PROPOSED CONSTRUCTION	PHS'S PROPOSED CONSTRUCTION
3	"disposable" or "disposing" (claims 1-4, 6-11, 17-20)	Plain and Ordinary Meaning	discarded after one use

With respect to this claim term, the parties dispute the necessity of further construing the terms "disposable" and "disposing." Larada argues that the terms have a common meaning that does

³ Following their briefing, the parties reached an agreement on several claim terms that had been disputed. This Order will number the disputed terms consecutively to avoid confusion but note the earlier disputed claim term numbers used by the parties in their briefing.

not limit “disposable” items to a single use (for example a disposable razor). PHS contends that the patent distinguishes between multi-use and single use applications and therefore it is necessary for the Court to make clear that “disposable” in the context of the patent refers only to the single use application, in part because someone reading the patent might be confused by other common meanings of the term “disposable” as suggested by Larada.

Based on the governing specification, the Court finds that PHS has the better argument on this term and that some clarification needs to be made to avoid the construction of “disposable” as permitting multiple uses when the patent intends to refer to only a single use. However, the Court’s construction should not undermine the embodiment disclosed in the specifications in which an applicator has a detachable or removable portion that could either be cleaned for re-use or disposed after a single use. Therefore, for the reasons discussed below, the Court will construe “disposable” as “intended to be discarded after a single use” and construe “disposing” or “disposed of” to mean “throw[n] away or discard[ed].”

In claim construction, the specification is “the single best guide to the meaning of a disputed term” and “[u]sually dispositive,” *Phillips*, 415 F.3d at 1315. *See Retractable Techs., Inc. v. Becton, Dickinson and Company*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) (“claim construction process entails more than viewing the claim language in isolation . . . [it] must always be read in view of the written description . . . we strive to capture the scope of the actual invention, rather than . . . allow the claim language to become divorced from what the specification conveys is the invention.”).

The ’510 Patent’s specification distinguishes between a multi-use applicator tip embodiment and a single-use applicator tip embodiment:

In embodiments having a **disposable portion**, the disposable portion of the applicator (or the entire applicator) **may be removed from the blower and discarded**. A new

applicator may then be used **in a subsequent treatment session on a new patient.** '510 Patent, 2:10-14 (emphasis added).

One or both of the base and the tip may be **disposable**. **Disposability** of at least a portion of the device that is to come in closest contact to a patient's skin may be desirable to avoid spreading disease, infestations, human tissue, and/or ectoparasite remnants from one patient to the next. For example, **in embodiments in which the tip is removable from the base, the tip may be disposable and configured for a single treatment session**, whereas the base may be reused in multiple treatment sessions. *Id.*, 3:48-56 (emphasis added).

In some embodiments, the applicator may be configured to **deter a user from using at least a portion of the applicator for more than one treatment session** or may be configured to provide an indication that the applicator (or a **disposable portion of the applicator**) has already been used in a treatment session. *Id.*, 3:56-61 (emphasis added).

As set forth above [after going through all the ways to discourage more than one use], in some embodiments, the device may be configured as a two-piece design **integrating a disposable tip**. Alternatively, a one-piece re-usable design may be provided. **In the latter embodiments, the piece may be cleaned and/or disinfected between uses**. As still another **alternative, a one-piece disposable design may be provided**. *Id.*, 5:7-12 (emphasis added).

In other embodiments, it may be preferred to embody the main design features in a single, essentially unibody component. Such a design can provide good durability, for example. A one-piece design may also have good potential to be **cleaned and re-used if that is desired, thereby offering the possibility of reduced cost when considered on a per-treatment basis and compared to a two-piece design with a disposable tip**. *Id.*, 5:43-50 (emphasis added).

See Baran v. Med.Device Techs., Inc., 616 F.3d 1309, 1316 (Fed. Cir. 2010). In *Baran*, the specification described both a multi-use component and, alternatively, a single-use component. *Id.* at 1312. The Court held that claims using terms from the specification describing the multi-use embodiment excluded the single-use embodiment. *See id.* at 1315 (“[t]he patentee used the term ‘detachably’ in the specification to draw a direct contrast between the removable components of the reusable embodiment and the adhesively bonded components of the single-use embodiment.”)

In response, Larada relies on the use of “may” language in the specifications referring to applicators that “may be disposable.” However, the use of “may” in this context appears more

accurately to distinguish between multi-use (i.e. non-disposable) and single-use (disposable) applications. Also, Larada relies on the following portion of the specification, which it argues specifically allows for the reuse or disposal of an applicator tip:

[a]n embodiment of an applicator having a detachable or removable portion **could** be used by removing the detachable portion of the applicator for cleaning and re-use. Alternatively, the detachable applicator tip **could** be disposed of properly as a single-use component.

See '510 patent at column 5, lines 28-32 (emphasis added).

However, this part of the specification does not support Larada's request for no construction of the "disposable" terms. Rather, it simply discloses an alternative embodiment in which an applicator tip can either be cleaned or thrown away. Significantly, the word "disposable" is not used in this description, which instead uses the words "detachable or removable" to describe the portion of the applicator than may be cleaned or thrown away. In other words, it might be "disposable" (intended to be thrown away after one use) or it might be cleaned and re-used. Thus, the construction of disposable as "intended to be discarded after a single use" is not inconsistent with this portion of the specification.

Finally, as noted above, Larada's reference to the common meaning associated with disposable razors and toothbrushes only emphasizes in the Court's mind the need for construction of the term "disposable." Disposable razors are not fully analogous to the invention at issue. In the context of the specification, the reason the portion of the applicator that touches the scalp might need to be disposable is to prevent cross-contamination and "avoid spreading disease, infestations, human tissue, and/or ectoparasite remnants from one patient to the next." '510 Patent, 3:49-52. In contrast, disposable razors and toothbrushes are not designed for use across multiple people, making the risk of spreading disease and contaminated human tissue low. More analogous to these circumstances is a disposable syringe that is intended only to be used once (but could be

improperly used multiple times). Therefore, the alternate common use of the term “disposable” to apply to “multiple but limited use” (such as with a plastic razor) counsels in favor of clarifying the term so that it is properly understood in the context of the ‘510 Patent.

Thus, **“disposable” is construed to mean “intended to be discarded after a single use” and “disposing” or “disposed of” are construed to mean “throw[n] away or discard[ed].”**

TERM 4 (referenced as Term 7 in the parties’ briefing):

	TERM (Patent: claims)	LARADA’S PROPOSED CONSTRUCTION	PHS’S PROPOSED CONSTRUCTION
4	“wherein the second applicator is configured for delivering airflow to a treatment site on the animal” (claims 1-4, 6-11)	Plain and Ordinary Meaning	Indefinite

PHS argues that disputed claim term 4 is also “indefinite,” but asserts a reason different than discussed above in connection with either the temperature or airflow terms of the ‘902 Patent. PHS contends that this term is indefinite because it “lacks an antecedent basis.” Specifically, PHS contends that the term “a treatment site” does not have a clear meaning in this claim because it is allegedly used “inconsistently” elsewhere in the patent. The Court disagrees with PHS’ argument and finds that a PHOSITA could understand with reasonable certainty the plain meaning of this term in the context of these claims.

In relevant part, claim 1 of the ‘510 Patent reads as follows:

A method for treating an animal having a lice infestation to substantially eliminate both lice and lice eggs from the animal, the method comprising:

obtaining an applicator . . . wherein the applicator is configured for delivering heated airflow to a treatment site on the animal;

delivering a heated airflow through the applicator to the treatment site to substantially eliminate the lice and lice eggs from the treatment site;

moving the applicator to a second treatment site;

delivering a heated airflow through the applicator to the second treatment site to substantially eliminate the lice and lice eggs from the second treatment site;

* * *

connecting a second applicator to the heated airflow source, wherein the second applicator is configured for delivering airflow to a treatment site on the animal.

See '510 Patent, Claim 1.

PHS' argument is that Claim 1 is indefinite because it is allegedly unclear what "treatment site" is referenced by the claim language related to "the second applicator." PHS' theory is that it is unclear whether the "second applicator" claim language refers to three different "treatment sites," with the first applicator delivering airflow to two of them ("a treatment site", "a second treatment site") and the second applicator delivers airflow to a third, different "treatment site," or whether the claim refers to two "treatment sites" with the first applicator delivering airflow to two of them ("a treatment site", "a second treatment site") and the second applicator also delivering airflow to one of those same treatment sites ("a treatment site" or "a second treatment site"). Thus, PHS' argument is that the claim's reference to the "second applicator" being "configured for delivering airflow to a treatment site" is indefinite because, allegedly, it creates confusion as to whether the second applicator delivers heated air to "the same 'treatment site' or some other additional treatment site."

Larada argues in response that PHS' argument ignores that when the claims refer to the first and second applicators being configured for "a treatment site" that is not a reference to an act of treating but to how the applicator is configured. *See* '510 Patent, claims 1-4 & 6-11. Therefore, the

claimed applicators are not *configured* for treating a particular site (even though once they are used on treatment sites, the “first” and “second” sites are of course specific sites). Larada concludes that it is clear that the second applicator is simply being configured for any site that has not already been treated (in other words, the cycle restarts with a “second” applicator after the disposable portion of the “first” applicator has been discarded).

Again, the critical inquiry is whether PHS has presented clear and convincing evidence that a PHOSITA would not be able to determine the steps of the invention claimed in the patent. The Court finds that a PHOSITA would be able with reasonable certainty to understand the patent steps in claim one of the ‘510 Patent so this claim language is not indefinite.

Specifically, claim one of the ‘510 Patent says that the method requires, “repeating the delivering and moving steps until substantially all the lice and lice eggs have been eliminated [from the first and second treatment sites]” ‘510 Patent at 10:28-29. Therefore, a PHOSITA would reasonably understand that there would be no need to return to either the “first” or “second” finished treatment sites, but instead would attach a different disposable portion to the applicator and go to a different site. And, if there was a reason to return to the earlier sites with a second applicator then that would still not mean that the patent was “indefinite.” Accordingly, the Court finds that disputed claim term 4 is not indefinite and need not be construed beyond its plain and ordinary meaning.

TERMS 5 and 6 (referenced as Terms 8 and 9 in the parties’ briefing):

TERM (Patent: claims)	LARADA’S PROPOSED CONSTRUCTION	PHS’S PROPOSED CONSTRUCTION

5	“the applicator tip delivers substantially all of the airflow to a single side of the applicator” (claim 6)	Plain and Ordinary Meaning	the applicator tip delivers all airflow to one, and only one, side of the applicator
6	“the airflow is delivered laterally of the applicator such that the treatment site extends from the applicator to only one side of the applicator” (claims 12-20)	Plain and Ordinary Meaning	the airflow is delivered laterally to only one side of the applicator such that the treatment site extends from the applicator to one, and only one, side of the applicator

The parties have addressed Terms 5 and 6 together so the Court will do the same. PHS’ proposed construction of these terms differs from Larada’s in two respects. First, PHS wants to remove the word “substantially” from Term 5. Second, PHS wants to add the words “and only one” to the terms, which it argues “clarifies” their meaning.

The asserted basis for PHS’s proposed changes is that Terms 5 and 6 should be limited because of arguments Larada made during patent prosecution to obtain the ’510 Patent. Prosecution disclaimer “preclude[s] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). When a “patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender.” *Id.* at 1324. For example, limiting the scope of a claim to overcome a prior art rejection results in “narrow[ing] the meaning of the claim consistent with the scope of the

claim surrendered.” *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013). Such disclaimer can occur through amendment or argument. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985).

However, for “prosecution disclaimer” to apply to the construction of a claim, the arguments made in the patent office must rise to the level of a “clear and unmistakable disclaimer” or an “unequivocal disavowal” of claim scope. *See Phillips*, 415 F.3d at 1316-1317. *See also Tech. Props. Ltd. V. Huawei Techs. Co.*, 849 F.3d 1349, 1357-58 (Fed. Cir. 2017) (“The doctrine does not apply unless the disclaimer is both clear and unmistakable to one of ordinary skill in the art. . . . If the challenged statements are ambiguous or amenable to multiple reasonable interpretations, prosecution disclaimer is not established.” (internal quotation marks omitted)).

PHS contends that Larada disclaimed being able to use “substantially” with respect to the delivery of airflow to “a single side of the applicator tip” when it argued that the claims in the ‘510 Patent could be patented over an earlier patent to Clayton (App. No. 11/133,067), which describes directing airflow in two directions—downward and laterally—from the applicator. *See* February 23 Office Action and Response, Doc. No. 26-4. To overcome the patent examiner’s initial rejection, Larada argued “Clayton does not disclose or suggest directing airflow laterally of the applicator such that the treatment site extends from the applicator *to only one side of the applicator*” because in Clayton “airflow is *directed downward* from the applicator through opening 70 *and simultaneously in the direction of arrow 72* through the top half of comb structure 68” rather than “laterally to only one side of the applicator as recited in claim 13.” February 23 Office Action and Response, Doc. No. 26-4 at p. 27) (emphasis added).

However, Larada also cited to the specification of the ‘510 Patent which explains:

. . . the airflow may be generally directed in a particular direction (two-dimensionally; e.g., when viewing the applicator in a plan view above the

treatment site, *the airflow substantially extends in only one of four primary directions, each of which is either orthogonal or opposite from the other three*). In some such embodiments, the airflow may be delivered *laterally of the applicator* (when viewed from overhead the applicator on the treatment site) such that the treatment site extends from the applicator *to only one side of the applicator*

'510 Patent, 2:8-17 (emphasis added). Therefore, while Larada did argue to the patent office that the '510 Patent's claims were directed to delivering air in only one direction, it did not go as far as PHS contends; instead, it limited its disclaimer by including the word "substantially" in its argument as it does in its claim language. Accordingly, the Court finds that Larada did not "clearly and unmistakably" disavow "substantially," as would be required for prosecution disclaimer.

PHS's other request – to add "and only one" to the claim terms – need be only briefly addressed. With respect to Term 5, adding this language would be inconsistent with the claim term "substantially," which is properly included as discussed above. And, with respect to Term 6, the language "only" is clear on its own and does not require any "clarification."

Therefore, the Court finds that Terms 5 and 6 should be given their "plain and ordinary" meaning and need not be further construed.

TERM 7 (referenced as Term 10 in the parties' briefing):

	TERM (Patent: claims)	LARADA'S PROPOSED CONSTRUCTION	PHS'S PROPOSED CONSTRUCTION
10	"wherein the ports are positioned on the fingers along substantially only one side of the fingers" ('510: 12-20)	Plain and Ordinary Meaning	Indefinite

	“the second treatment site extends from the applicator to substantially only one side of the applicator” (claims 12-20)		
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The parties’ final disputed claim term again raises the issue of “indefiniteness.” Specifically, PHS contends that the language “along substantially only one side” is indefinite because taken literally “substantially only” is inherently contradictory because something cannot be simultaneously “only” (“solely”) and “substantially” (“largely but not wholly”). Thus, PHS argues, resolving the alleged contradiction requires rendering either the word “substantially” or “only” superfluous, which “. . . render[s] the scope of the patent ambiguous, leaving examiners and the public to guess about which claim language the drafter deems necessary to his claimed invention and which language is [a] merely superfluous, non-limiting elaboration.” *Bicon, Inc.*, 441 F.3d at 950.

While a claim term is indefinite when it “is open to multiple interpretations reflecting markedly different understandings of the patent’s scope,” *Nautilus*, 134 S. Ct. at 2131, the relevant test, as discussed above, is whether the term “substantially only one side” is so ambiguous that it fails to “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Id.* at 2129. At this stage of the proceedings, and giving meaning to the standard of proving invalidity by “clear and convincing evidence,” the Court finds that a PHOSITA would be able with reasonable certainty to interpret the “substantially only” claim language to mean that the ports are positioned largely but not entirely on one side of the applicator’s fingers and that the treatment site is similarly largely but not entirely on one side of the applicator.

While an absolute literal meaning of “substantially only” might be contradictory, a PHOSITA (who will be an engineer or entomologist but not likely a linguist), would read the claim

language “only” as merely emphasizing that the positioning of the ports relative to the fingers and the direction of the treatment site is to be on a single side of the applicator, with some flexibility in accordance with the word “substantially.”⁴ Read fairly in this manner, both the words “substantially” and “only” would have some meaning, even if the word “only” might have been omitted without significantly changing the ultimate practical effect of the claim language.

Therefore, the Court finds that disputed claim term 7 is not indefinite and there is no need to construe this term beyond its “plain and ordinary” meaning.



Kenneth D. Bell
United States District Judge



Signed: August 26, 2019

⁴ Indeed, PHS suggested in connection with Terms 5 and 6 that the Court construe those terms to add “and only one” as a “clarification” of the “one side” language.